DRUG UTILISATION STUDY TO ASSESS THE PATTERN, PHARMACOECONOMICS AND RATIONALITY IN PERIODONTICS DEPARTMENT OF DENTAL COLLEGE(S) OF HIMACHAL PRADESH

SYNOPSIS OF THE THESIS

Submitted by

Dharmesh Sharma

Registration No 18RCPPHP004

Under supervision of

Dr. Amit Chaudhary

In Partial Fulfillment of the Requirements

for the Degree of

DOCTOR OF PHILOSOPHY

SCHOOL OF PHARMACY

FACULTY OF PHARMACY

ABHILASHI UNIVERSITY

CHAILCHOWK, MANDI (H.P.) 175028

DRUG UTILISATION STUDY TO ASSESS THE PATTERN, PHARMACOECONOMICS AND RATIONALITY IN PERIODONTICS DEPARTMENT OF DENTAL COLLEGE(S) OF HIMACHAL PRADESH

SYNOPSIS OF THE THESIS

Submitted by

Dharmesh Sharma

Registration No 18RCPPHP004

Under supervision of

Dr. Amit Chaudhary

In Partial Fulfillment of the Requirements

for the Degree of

DOCTOR OF PHILOSOPHY

SCHOOL OF PHARMACY

FACULTY OF PHARMACY

ABHILASHI UNIVERSITY

CHAILCHOWK, MANDI (H.P.) 175028

DECLARATION

I hereby declare that the dissertation synopsis entitled "**Drug utilization study to assess the pattern, pharmacoeconomics and rationality in Periodontics department of dental college(s) of Himachal Pradesh**" to be submitted for the partial ulfillment of the Degree of Doctor of Philosophy is my original work and the dissertation has not formed the basis for the award of any degree, diploma, associateship or fellowship of similar other titles. It has not been submitted to any other University or Institution for the award of any degree or diploma.

Dharmesh Sharma.

Place: CHAIL CHOWK

Signature of the Scholar

Date: 10/04/2021

Dharmesh Sharma

Forwarded by: Concern Supervisor

Place: Chail Chowk.

Signature of the supervisor

Date: 10.04.2021

Dr. Amit Chaudhary
Professor
School of Pharmacy
Abhilashi University
Chail-Chowk, Distt. Mandi (H.P.)

Approved

Dean
School of Pharmacy
Abhilashi University
Chail-Chowk, Distt. Mandi (H.P.)
12/4/2021

INDEX

Introduction	**1-2**
Review of literature	**3-5**
Objective	**6**
Research Methodology	**7-9**
Tentative chapter plan	**10**
Annexure	**11-12**
Reference	**13-14**

INTRODUCTION

Drug utilisation study plays a powerful mechanism to determine the use of drugs in medical practice and build the foundation of economic bases in a health care system. Evaluation of prescription pattern in health care system help to distinguish obstacles in rationalising drug use. (1) The Drug utilisation is defined by the world health organisations "the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences"(2) The data of drug utilisation help in the development of health policies. It is used to estimate the variations in requirements, the option of drugs in prescription, price variations in treatment with reference to other countries also.(3) Drug utilisation studies would also help to access the rationality of drug usages. It analyses the existing situations and help to improve the drug usage in the healthcare system at various levels whether in community, facility or national level.

A doctor prescribes drugs in the form of written advice mentioning drugs name, adequate dose, duration, and instructions to pharmacists to dispense the drug to patients. Rationality in prescription plays a major role in wellbeing of patient and affects the psychosocial and financial state as well. It also helps in reducing drug interactions, adverse drug reactions, and extra burden on health workers. Irrational drug prescription can lead to over or under prescription, polypharmacy and drug resistance development. Many studies showed wide variations in pattern of drug prescribing at hospital and community level. The cause of this variability can be due to lack of standard treatment guidelines or lack of knowledge. Inadequate management and irrational use of drugs increases the disease burden, mortality and the misuse of resources. Therefore, it is important to understand negative outcomes of inappropriate drug usage to promote rationality in drug use.(2)

Pharmacoeconomics is a scientific discipline to compare the treatment policies and pharmaceutical products on the bases of cost minimisation, cost-effectiveness, cost-utility, and cost of illness. It also assists scientific and standardised to manage the optimum allocation of resources in health care. Currently, it is practised to make formulary decisions, management of the disease designing plans, and cost-effectiveness. (3,4)

In India data concerning drug usage pattern study in dentistry is lacking. There are various branches under Dental sciences and the management requires a variety of drugs including analgesics, antibiotics, antacids, vitamins, and other drugs. (2)

Periodontics is one of the branches of dentistry that deals with diseases of the supporting and investing structures of the teeth which include the gingiva, cementum, periodontal membrane, and alveolar bone. Periodontists provide treatments for scaling and root planning along with root surface debridement and prevention of periodontal disease. They also take care of dental implants along with diagnosis and problems. (5)

This drug utilisation study is planned in the department of periodontics with the objective to study the pattern of drugs used, cost of treatment, quality of life during and after the treatment and to determine the rationality of prescription to identify the areas that need to be targeted to improve the patient care and resource allocation further.

LITERATURE REVIEW

Historical Development

The origin of drug utilisation studies can be outlined since 1960s. In the beginning the attention was given to community based drug utilisation study. (6) Thalidomide disaster was a hot topic at that time and people recognise that they did not have any scale to assess the risk of medicinal products. A study on drug consumption was carried in six countries of Europe in 1966 and a vast difference was found in drug usage pattern. That also confirmed the requirement of a classification system for presenting drug consumption data. The concept of drug utilisation study was originally from northern Europe and then it was followed by the rest of the world. First, it was based on economic considerations, and then it also included the effectiveness, efficiency and safety of drug usage. In North America, these studies were performed at an individual level in hospitals and in ambulatory care. They mainly focused on a particular prescriber and patients as required for the study. A drug research review study also confirms the optimisation of therapy for patients and can be used as a tool to assure quality. In Europe and in Scandinavia these studies started with calculating sales records. This helped them to find out the quality of the drugs and allowed to compare with other geographical areas. (7)

The Alma Ata declaration on primary health care in 1978 stressed the requirement of essential drugs and in the same year, regional office for Europe of world health organisation also published the first book on Drug utilisation study. In November 1985 a meeting was held in Cologne, Germany to review current research trends and future by the World Health Organization drug utilisation research group. In 1986 Drug Utilization Biography was published by the centre for drug statistics with the World Health Organization which contained 709 published papers from 1981 to 1986. At the same time, World health organisation international monitoring centre at Uppsala was given the responsibility to coordinate drug utilisation research in various countries. Since then countries of the world are giving importance to drug utilisation studies and have published their essential drug lists. (6)

Aspects of drug utilisation Study

Drug utilisation pattern studies are based on the three aspects: medical, social and economic aspects. Medical aspects of drug utilisation analysis concentrate on the efficacy

of drugs in preventing, alleviating the disease as well as adverse effects of drugs and management. It can be used to improve our perception of how drugs are being used properly. These studies can also find out, what happens to the patient after the medication prescribed. Social aspects constitute patient perspective to drugs, drug misuse, dependency, incorrect use of drugs and unavailability of essential medicine to those who require them. Pharmacoeconomics is the sciences that estimate the values of drug treatment. The goal of Pharmacoeconomics is to choose least expensive and most productive drug therapy for a disease condition.(8)

Diseases of the oral cavity can disturb the well-being and self-confidence of a person. Oral health quality of life studies becomes a tool to understand and develop clinical practice following patient's behaviour. (9)

Drug utilisation studies in dentistry

Shrestha et al., **(2020)**, conducted a descriptive cross-sectional study in the Dental Outpatient Department of Dhulikhel Hospital, Kathmandu University Hospital. They found drug utilisation with brand names were frequent. The antibiotics were overprescribed and very fewer drugs were prescribed from the National essential drug list.(10)

Inder et al., **(2019),** conducted a prospective, cross-sectional study at the dental outpatient department of a teaching Institution, in south Delhi, India. They found polypharmacy, over-prescription of antibiotics. The prescription pattern was not according to WHO core indicators. Awareness about the National essential medicine list was good. (11)

Haliti et al., **(2017),** conducted a retrospective study in primary dental care in Kosovo. Findings were the over-prescription and irrationality in the antibiotics prescriptions.(12)

Patel et al., **(2016),** conducted a study to evaluate the prescription pattern at the dental hospital, Gujarat. In findings, no polypharmacy was found and most drugs were prescribed from the essential drug list. Drugs with generic names were less. (13)

Datta et al., **(2015),** conducted a drug utilisation study among the outpatients in the oral medicine department of Saveetha Dental College, Tamil Nadu, India. They found generic drugs prescribed were very less.(14)

Jayanthi et al., **(2014),** carried a retrospective study at J.S.S Dental College & Hospital, Mysore. They found most of the drugs in prescriptions were rational.(3)

Sharma et al., **(2014),** carried a prospective cross-sectional study at the Department of Pedodontics and Preventive Dentistry and Orthodontics in teaching hospitals in Rajasthan, India. They found fewer drugs were prescribed with generic names. Most of the antibiotics were prescribed for prophylactic purposes and less were for therapeutic purposes. (15)

OBJECTIVE

Drug utilisation study to assess the pattern, Pharmacoeconomics and rationality in periodontics department of dental college(s) of Himachal Pradesh

Primary Objective

To evaluate the drug utilisation pattern and rationality of prescription.

Secondary objective

1. To determine the cost of prescription in order to study the pharmaco-economic aspect of the treatment.
2. To compare the quality of life of patient during and after the treatment.

RESEARCH METHODOLOGY

Study Design

This drug utilisation study was prospective, cross-sectional and longitudinal for the quality-of-life assessment.

Study centre

Department of Periodontics of Himachal Dental College Sunder Nagar, District Mandi.

Sample

The study population will include new patients who underwent the oral treatment and received the medications during the study period in the department of periodontics and fulfil the inclusion and exclusion criteria.

Inclusion criteria

Patients willing to participate in the study will be included in the study.

Patients who will have all prescription information at the completion of treatment.

Patients consuming tobacco, or smokers, or those consuming alcohol, or pregnant ladies.

Exclusion criteria

Patients referred to other faculties or hospitals and not completed follow up

Study approval

This study will be conducted after taking the approval from Institutional Ethics Committee.

Sources of data/ tool

Patient case records, prescription and lab test reports and patient/ caretaker interview

Data collection and Statistics

As per the WHO guidelines, a minimum of 600 prescriptions are needed for a significant result. So, after reviewing the literature and based on systematic random sampling, more than 600 medical records of patients will be prospectively analysed, thereby fulfilling the desired criteria. The gathered data will comprise of the patient's demographical

components i.e., OPD number, age, sex, health problem description, Prescription parameters, such as drug name, route, strength, dosage form, amount, and duration, whether the drugs were prescribed in a generic name or not, will be evaluated. We will also evaluate the WHO core drug prescribing indicators, i.e., the average number of drugs per encounter, percentage of drugs prescribed by generic names, percentage of encounters with an antibiotic, percentage of encounters with an injection, and the percentage of drugs prescribed from the essential drug list (The National List of Essential Medicines (NLEM) 2015 of India). All the information will be recorded in the data collection form which is designed according to WHO guidelines. Data will be entered and coded, in Microsoft Excel version 2010. Then it will be exported to SPSS (IBM SPSS Statistics for Windows, Version 23.0; IBM Corp., Armonk, NY, USA) for data analysis. All variables will be analysed for descriptive statistics and expressed in frequency and proportions as the data will be continuous and nominal respectively. Further the calculations for prescription indicators will be carried out.(16)

1. The average number of drugs per encounter (C)
   First count the number of encounters for which data were collected, even if no drugs were given (A). For a basic indicator survey, this number will usually be 30. Then add up the total number of drugs prescribed during these encounters (B). Divide the total number of drugs by the number of encounters (A) and express the result with one decimal.
   Formula: Average number of drugs C=B/A
2. Percentage of drugs prescribed by generic name (E)
   Divide the total number of generic drugs prescribed (D) by the total number of drugs prescribed (B), and multiply by 100 to make a percentage (E).
   Formula: % Prescribed as generic E =(D/B) x 100%
3. Percentage of encounters with an antibiotic prescribed (G)
   Divide the total number of patients who received one or more antibiotics (F) by the total number of encounters (A) and multiply by 100 to make a percentage.
   Formula: % Antibiotics G = (F/A) x 100%
4. Percentage of encounters with an injection prescribed (I)
   Divide the total number of patients who received one or more injections (H) by the total number of encounters (A) and multiply by 100 to make a percentage.
   Formula: % Injections I=(HA) X100%

5. Percentage of drugs prescribed from essential drugs list or formulary (K)
   Divide the total number of EDL drugs prescribed (J) by the total number of drugs prescribed (B) and multiply by 100 to make a percentage (K).
   Formula: %Drugs from essential drugs list K = (J/B) X 100%
6. Percentage of patients treated without drugs (N)
   Divide the number of consultations in which no drug is prescribed (M) by the number of consultations surveyed (A) and multiply by 100 to make a percentage
   Formula: % Patient treated without drugs N= (M/A) X 100%
7. Average drug cost per encounter (P)
   Divide the total cost of all drugs prescribed (R) by the number of encounters surveyed (A)
   Formula: Average drug cost per encounter (P) P= R/A
8. Percentage of drug costs spent on antibiotics
   Divide the cost for all antibiotics or injections by the total drug cost and multiply by 100

To study the pharmaco-economic aspect of the treatment Cost of each drug will be considered from Index of Medical Specialists (MIMS) and currency used will be INR.

The questionnaire used to compare the quality of life of patient during and after the treatment included patient's personal and demographic information (age, gender, occupation, education, income, smoking, etc). Modified Oral Health Impact Profile instrument to evaluate quality of life before treatment and then two weeks after completion of periodontal treatment.(17) If patient will not able to come after treatment data will be collected telephonically.

Finally, the results will be interpreted, compared with WHO Criteria and then presented in the form of tables and graphs.

Outcome of the study

Prescription Pattern

Prevalence of periodontal diseases among the patients according to gender. The percentage of prescribed drug in each category of drugs will be calculated.

Drug utilisation pattern will be compared with the government settings with respect to the drug molecule being prescribed if they allow to access their data.

To Compare the safety profile of the drug, we will consider the value of prescribed daily dose and compared it with defined daily dose of the drug.

Rationality of prescription

To evaluate the rationality of prescription data will analyse by using WHO drug prescribing indicators

i. Average number of drugs per encounter.
ii. Percentage of drugs prescribed by generic names.
iii. Percentage of encounters with an antibiotic/injection prescribed
iv. Percentage of drugs prescribed from National list of essential medicines 2015

The results will be compared with the ideal values recommended by world health organisation for each core indicator except the essential drug list for which reference document shall be EDL of India.

Pharmacoeconomics

The outcome of the study will find the cost of over used category of drugs, average cost of prescription.

Quality of life

The assessment of the quality of life during and after the treatment and satisfaction of the patients after their periodontal treatment.

This study will determine the benefit, risk and cost-effectiveness in treatment and suggest overuse and underuse and misuse of medicines. The outcome of the study can help in the promotion of optimal prescription practice.

TENTATIVE CHAPTER PLAN

Acknowledgement

Content

Table/Graph

List Picture/Maps

List Abbreviations

Chapter I Introduction

i. Introduction
ii. Statement of problem
iii. Importance of the problem
iv. Aims and objectives of research
v. Research Methodology
vi. Introduction of study area

Chapter II Review of literature

Chapter III Data collection and analysis.

Chapter IV Conclusion

Findings Conclusion Recommendation Suggestions

Bibliography

ANNEXURE

DATA EXTRACTION FORM

Patient Name……

Age……

Gender…….

Educational qualification

Illiterate/ primary school/ high school/ graduate/ other

Occupation

Business/government employee/ house wife/ dependent/ retired/ other

Ration Card

BPL/APL

Social Habits

Cigarette/ tobacco/ other

Smokers- smoked ≥ 100 cigarettes in their lifetime and currently smoke

Former smokers-smoked ≥100 cigarettes in their lifetime and currently do not smoke

Non-smokers- not smoked ≥ 100 cigarettes in their lifetime and currently do not smoke

Alcohol

Yes/ no

Frequency and duration

Occasionally / once in a week / twice in a week / every day

Duration

1-5 year/ > 5 and <10 years / ≥ 10 years and more

		Never	Hardly ever	Occasionally	Often	Very often
	Functional limitation					
1	Trouble pronouncing words					
2	Less flavour in food					
	Physical pain					
3	Uncomfortable to eat					
4	Pain in oral area					
	Physical disability					
5	Difficult chewing					
6	Interrupt meals					
	Psychological disability					
7	Upset					
8	Being embarrassed					
	Social disability					
9	Trouble getting on with others					
10	Unable to work					
	Handicap					
11	Life less satisfying					
12	Unable to function					

DETAILED INDICATOR ENCOUNTER FORM

Health problem	Health problem description				
	1				
	2				
	3				
Drug Name	Route	Strength	Dose	Quantity	Duration

PRESCRIPTION INDICATOR FORM

LOCATION							
INVESTIGATOR							
SEQ	DATE	AGE (YEARS)	DRUGS	GENERIC	ANTIBIOTICS	INJECTIONS	ON EDL
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

REFERENCE

1. Yadav P, Kanase V, Lacchiramka P, Jain S. Drug utilization trends in ent out patient department in a teaching hospital. Int J Pharma Bio Sci. 2010;1(4):P153–60.
2. World Health Organization. Introduction to Drug Utilization Research. 2003.
3. Jayanthi MK, Sushma Naidu V. Drug utilisation pattern and pharmacoeconomic study in paediatric dentistry at a tertiary hospital. Int J Pharm Pharm Sci. 2014;6(2):70–2.
4. Gattani SG, Patil AB, Kushare SS. Pharmacoeconomics review. Asian J Pharm Clin Res. 2009;2(3):15–26.
5. TTariq M, Iqbal Z, Ali J, Baboota S, Talegaonkar S, Ahmad Z, et al. Treatment modalities and evaluation models for periodontitis. Int J Pharm Investig. 2012;2(3):106–22.
6. Dukes MNG. Drug utilisation studies. Methods and uses. Introduction. World Health Organization Regional Publications - European Series. 1993.
7. Truter I. A review of drug utilisation studies and methodologies. Jordan J Pharm Sci. 2008;1(2):91–104.
8. Meena DK, Jayanthi M. Drug utilisation research: a review. Int J Basic Clin Pharmacol. 2019;8(2):354.
9. Bennadi D, Reddy CVK. Oral Health Related Quality Of Life: Perspectives. J Int Soc Prev Community Dent. 2013;3(1):1–6.
10. Shrestha R, Shrestha SS, Koju S, Humagain M. Study of dental disease pattern and drug utilisation evaluation among patients visiting dental outpatient department of tertiary care centre. J Chitwan Med Coll. 2020;10(1):19–23.
11. Inder D, Kumar P. International Journal of Pharmacognosy and Chinese Medicine A Study of Drug Utilization Pattern (DUP), at Dental Outpatient Department of a Teaching Institution, in South Delhi, India. Int J Pharmacogn Chinese Med. 2019;3(2):1–5.

12. Haliti N, Krasniqi S, Begzati A, Gllareva B, Krasniqi L, Shabani N, et al. Antibiotic prescription patterns in primary dental health care in Kosovo. Fam Med Prim Care Rev. 2017;19(2):128–33.

13. Patel PS, Patel SN, Bhave A. Evaluation of prescribing pattern at dental outpatient department at a hospital, Gujarat. Natl J Physiol Pharm Pharmacol. 2017;7(1):47–50.

14. Pratiti D, Datta PP. Drug utilisation pattern in oral medicine department of Saveetha Dental College, Tamil Nadu, India. Natl J Med Res. 2015;5:272–4.

15. Sharma M, Tandon S, Chugh T, Sharma S, Parmod PS, Aggarwal V, et al. Drug abuse in paediatric dentistry: A cross-sectional study. J Clin Diagnostic Res. 2014;8(3):205–7.

16. How to investigate drug use in health facilities. Selected drug use indicators. World Health Organization; 1993.

17. Brauchle F, Noack M, Reich E. Impact of periodontal disease and periodontal therapy on oral health-related quality of life. Int Dent J. 2013;63(6):306–11.

Signature of the Scholar
Dharmesh Sharma

Signature of the Supervisor
Dr Amit Chaudhary